



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Autoclave Cum Bung Processor.

2.0 SCOPE:

This SOP is applicable for Operation and cleaning of Autoclave Cum Bung Processor (Make: **Machine Fabrik**) at

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production.

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

6.1 Before start operating, check the cleaning of the machine.

6.2 Before starting the machine check the utility services and ensure the availability of the same as per the table below.

Electricity	Power : 415 V-3 PH-50 Hz AC, 4 Wire Supply Control : 230 V-1 PH-50 Hz Stabilize AC Supply
Pure steam for jacket /chamber (Dry & Saturated)	Pressure: 1.5 – 2.5 kg/cm ²
Purified Water	Pressure: 1.5 -2.5 kg/cm ²
Process Air (Fluidization) Oil Free	Pressure: 5- 7 kg/cm ²

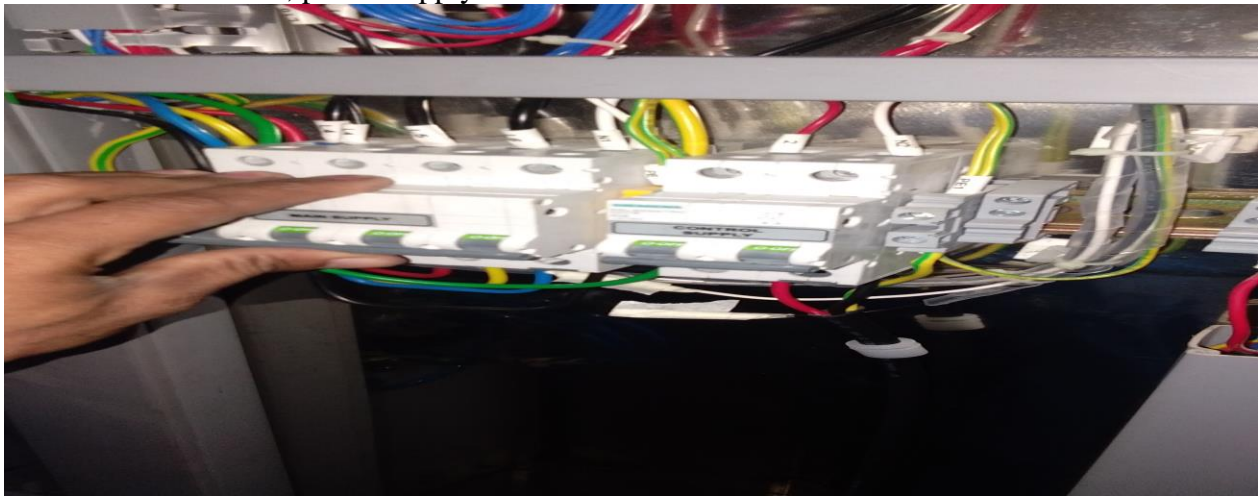


STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Compressed Air Lubricated (Dry & Saturated)	Pressure: 5 – 7 kg/cm ²
Process Water (WFI)	Pressure: 1.5-2.5 Kg/cm ²
Soft Water For vacuum System	Pressure: 1.5-2.5 Kg/cm ²

6.3 Switch "ON" the main, power supply.



6.4 Switch "ON" the control button or HMI.



6.5 HMI Display.

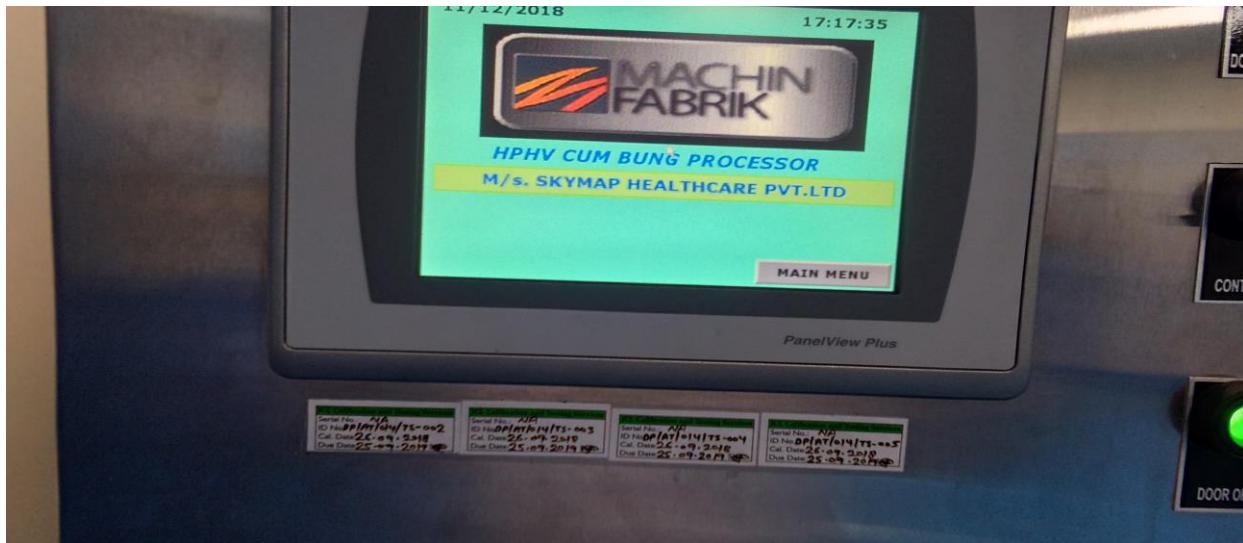


PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



6.6 Press the main menu.



6.7 Main menu appears as under.

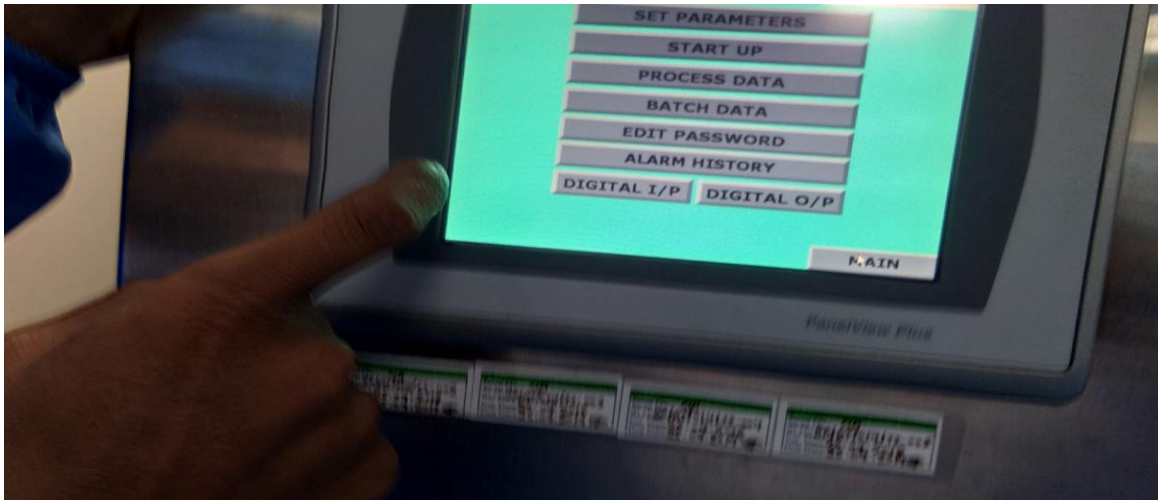


PHARMA DEVILS

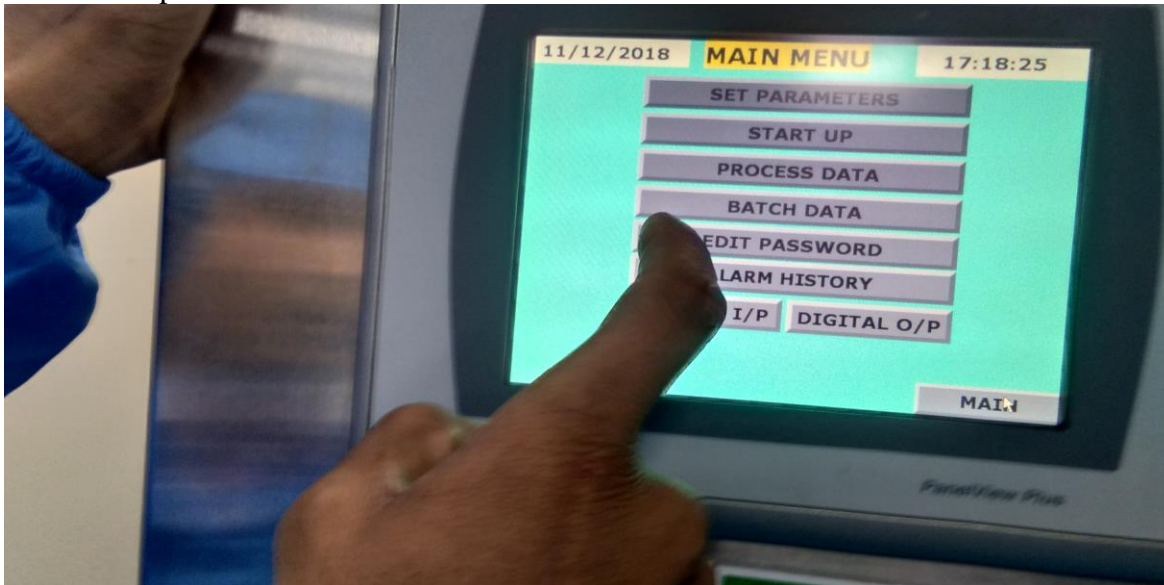
PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



6.8 Press edit password.



6.9 Current user display on screen.

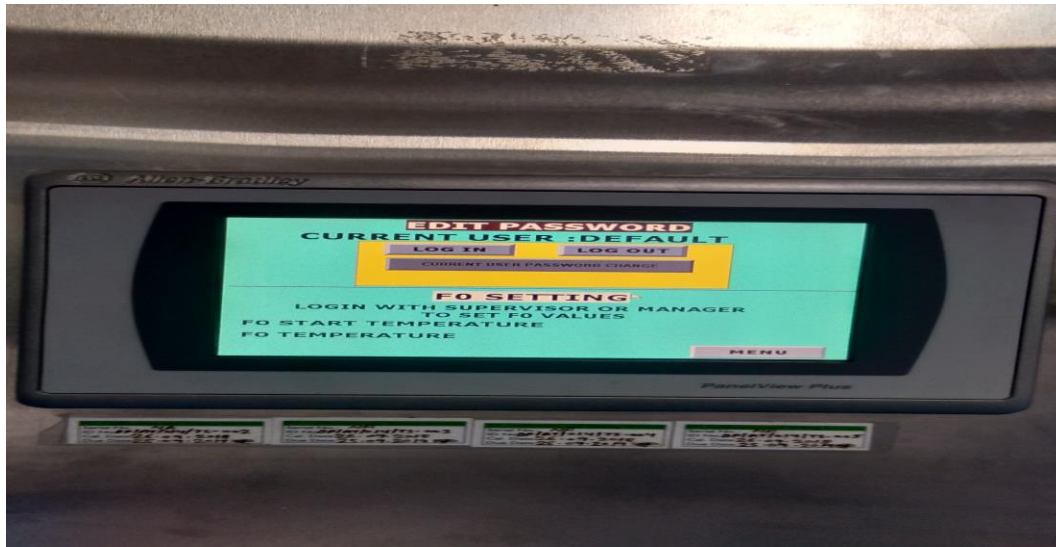


PHARMA DEVILS

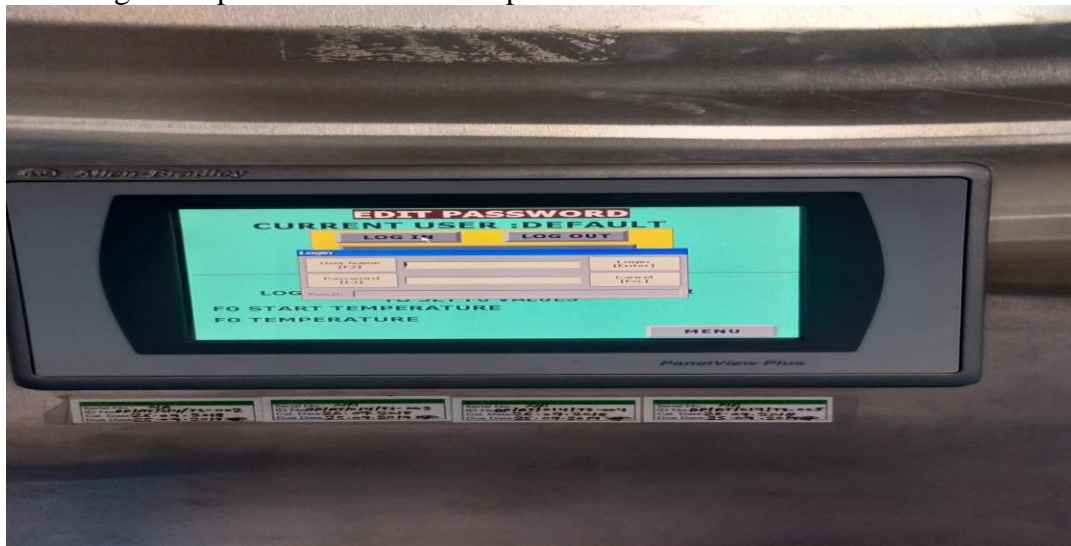
PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



6.10 Press login and put the user name and password.



6.11 Press main menu

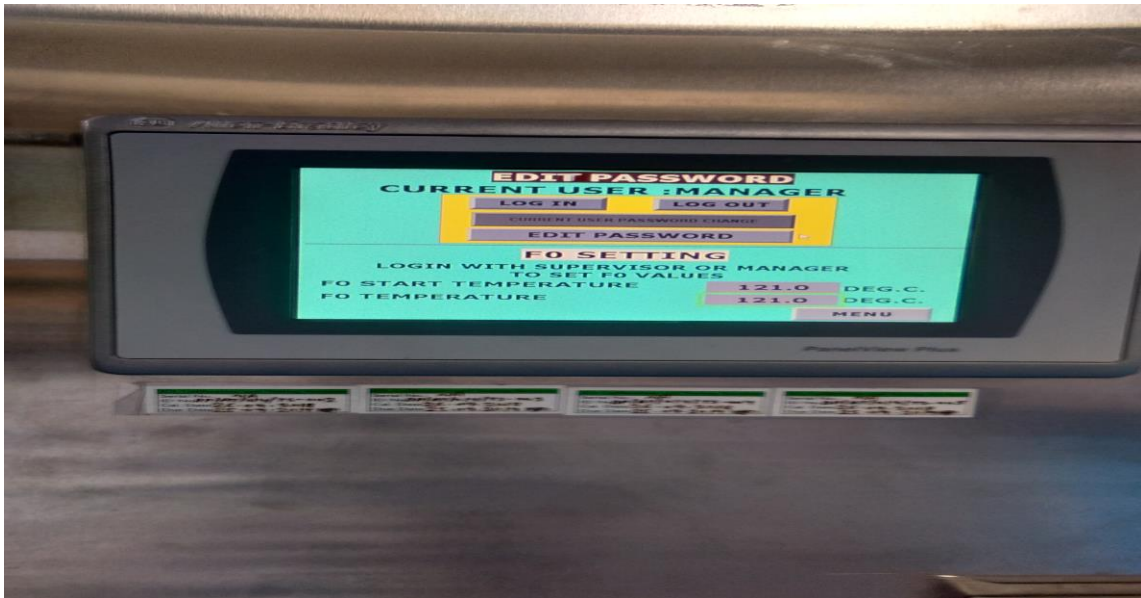


PHARMA DEVILS

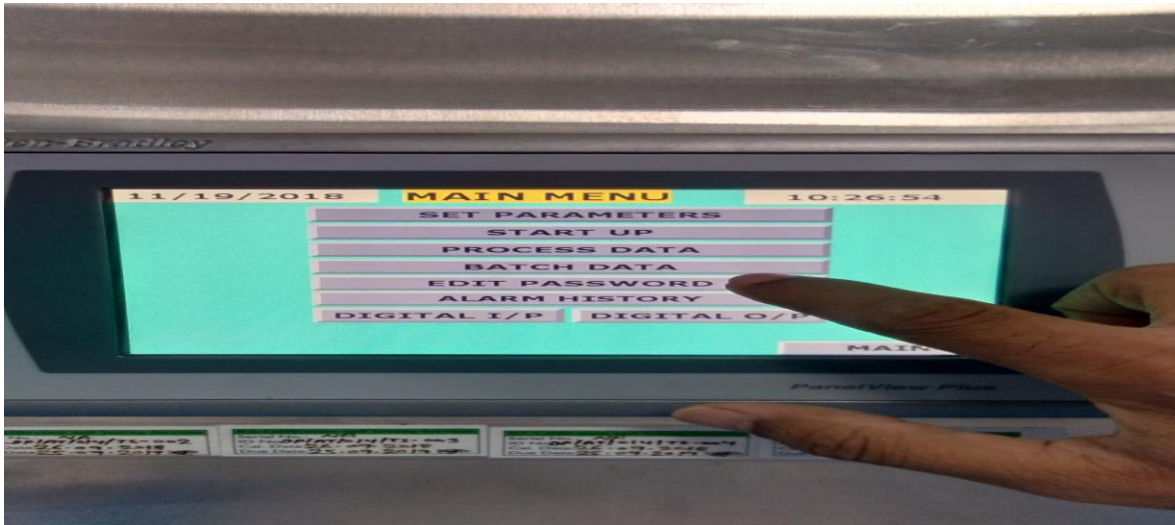
PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



6.12 Press the button of batch Data.



6.13 Enter the batch data.

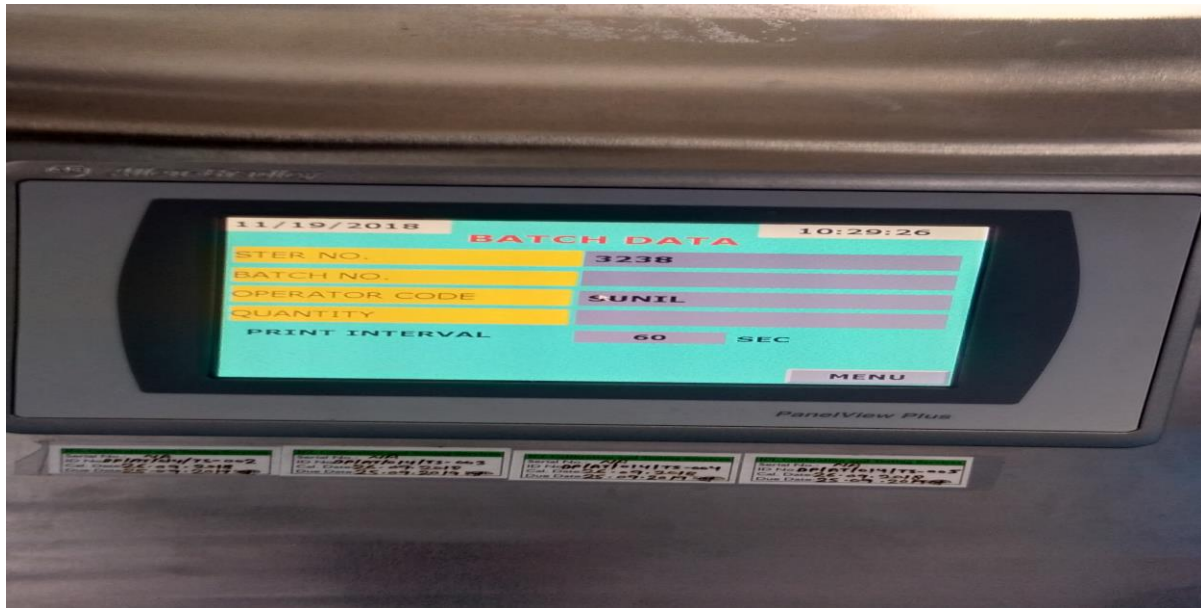


PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



6.14 Press startup. For respective cycles.



6.15 Selected process display on screen.



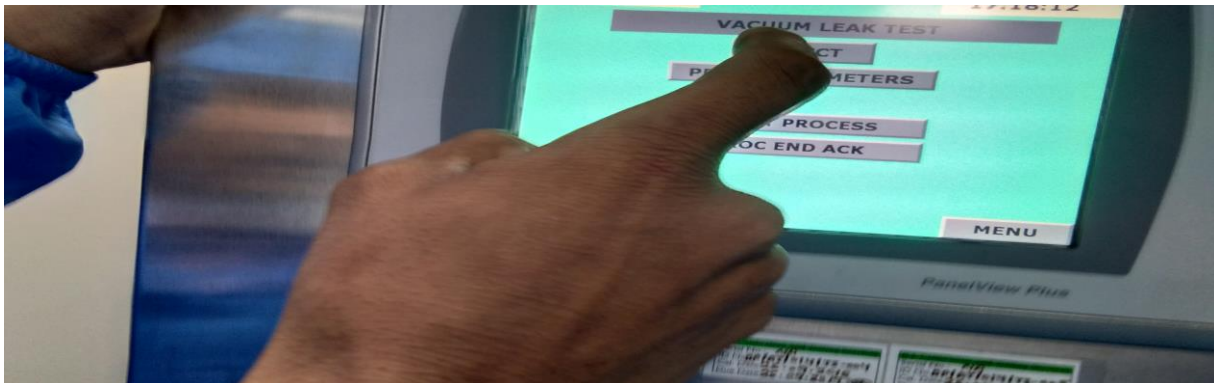
STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



6.16 Press the select button for cycles.

1. VLT
2. Warm-up cycle
3. Standard process
4. Bowie dick test
5. HPHV Process
6. Bung processor
7. HLT

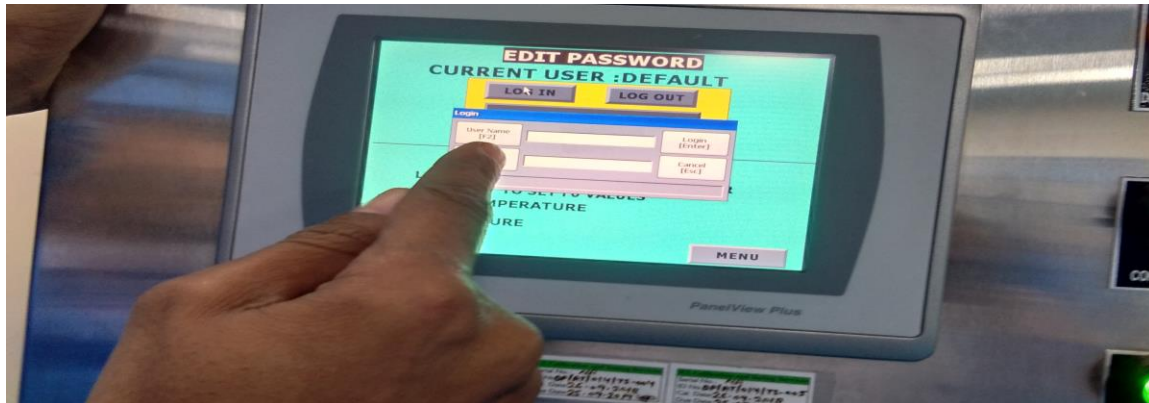


6.17 Enter the login id and password.

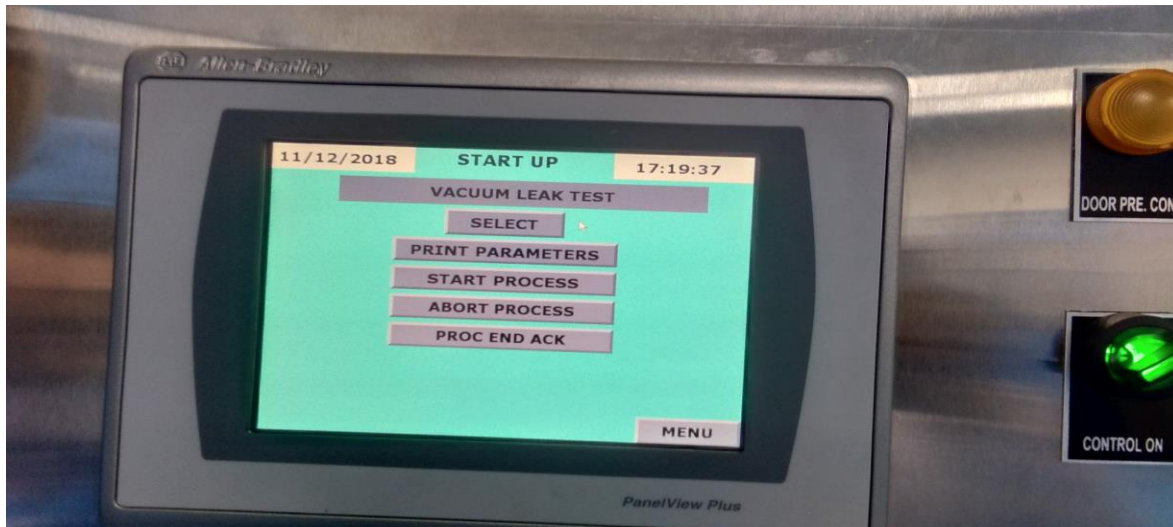


STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



6.18 Push print parameter to command the print



6.19 Press the start process.

6.20 HMI Display The Process Data.

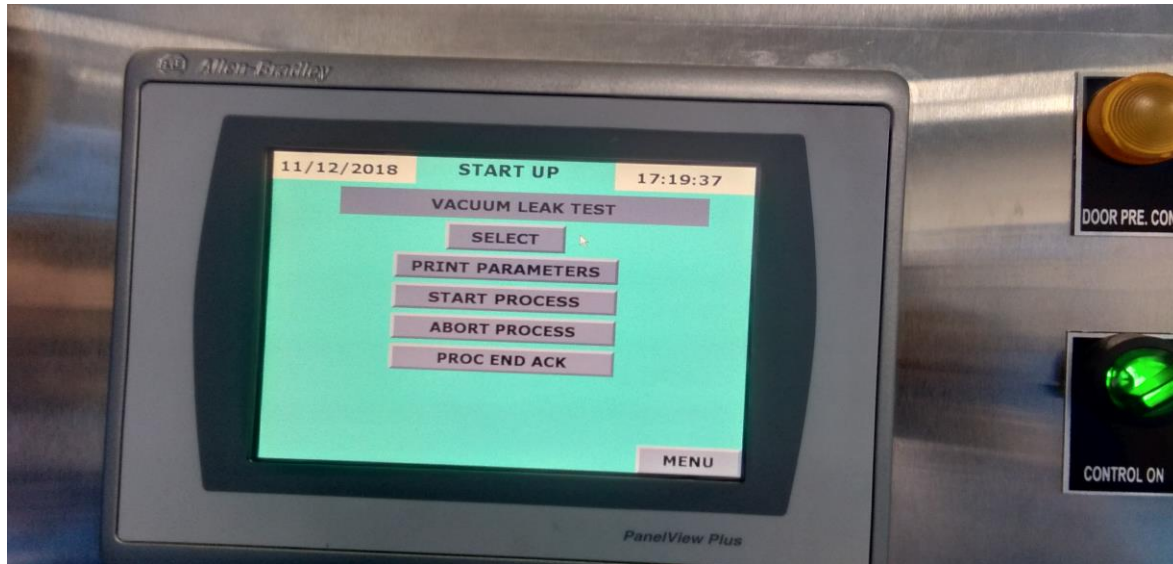
6.21 After completion of cycle process end display on screen

6.22 Press process end Ack.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



- 6.23** The selected process will run according to the process parameters saved in the system. If power supply discontinued during run, process will be stopped. After power resume the system will start automatically and the process will resume.
- 6.24** After completion of the cycle the “**ALARM**” will blink and the buzzer will start.
- 6.25** Manually open the door from sterile side and unload the sterile articles.
- 6.26** Autoclave Cum Bung Processor can also be operated through “**Manual Mode**” in case of any break down of PLC.
- 6.27** “**Manual Mode**” operation can be executed by operating all the utility services manually, switch provided on the panel.
- 6.28** For manual mode operation all the pre operation checks are as same as auto mode operation.
- 6.29** During manual mode operation thermograph recorder and temperature display will be functioning but HMI, temperature recorder and printer will not work.
- 6.30** Temperature and pressure at different time interval shall be recoded manually by viewing readings displayed on the temperature display and pressure gauges.
- 6.31** Schematic representation of the device to operate the equipment manually is as under.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Autoclave Cum Bung Processor

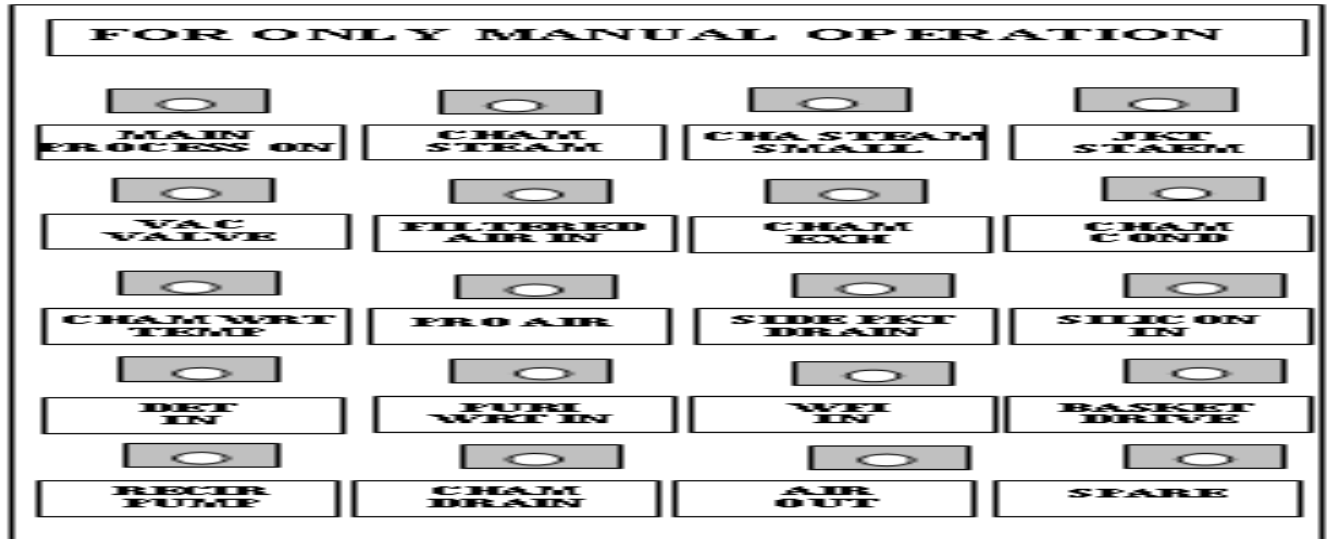
Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



6.32 In case of acute emergency, press “EMERGENCY” button. The cycle will stop where it is. To start the machine again follows the same process stated from point number 6.1 onwards. “EMERGENCY” button should be used only in case of high degree of emergency needs such as saving human lives, fire, electrical short circuit, accident etc.

6.33 CLEANING OF AUTOCLAVE CUM BUNG PROCESSOR:

6.33.1 Wipe off outside body of the Autoclave cum Bung processor with mopping pad.

6.33.2 Wipe off all the pipe connections.

6.33.3 Take out drain cover screen; Scrub it thoroughly using nylon brush and 0.2% SLS (Sodium Lauryl Sulphate) Solution Wash it with water thoroughly.

6.33.4 Clean the chamber and door with 0.2% SLS solution using mopping pad, hot water and Nylon Brush. Wash thoroughly with Purified Water followed by final rinse with WFI.

6.33.5 Wash the trolleys and shelves with 0.2% SLS solution and then with Purified water. Finally rinse it with WFI.

6.33.6 Record the Cleaning details in



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.33.7 For Cleaning of Detergent and Silicon reservoir, Remove the detergent and silicone reservoir from the bung processor by removing the TC clamp Scrub it thoroughly using nylon brush and 0.2% SLS Solution and finally rinse it with sufficient quantity of water for injection.

6.34 CLEANING FREQUENCY:

6.34.1 After product change over and once in a day in case of equipment not in use.

6.34.2 Detergent and silicon reservoir shall be cleaned fortnightly.

6.35 Record the Operation details of Vacuum Leak Test of Autoclave cum Bung Processor in the **Annexure-I**, Titled “**AUTOCLAVE CUM BUNG PROCESSOR OPERATION & CLEANING LOG BOOK**”.

6.36 Record the Operation details of Bowie Dick test in Annexure I.

7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
QA	Quality Assurance
No.	Number
Ltd.	Limited
WFI	Water for Injection
ID No.	Identification Number
Kg	Kilogram
cm	Centimeter
WFI	Water for Injection
SLS	Sodium Lauryl Sulphate
Sec.	Second
Min.	Minutes
°C	Degree Celsius
HPHV	High Pressure High Vacuum
PLC	Programmable Logic Controller



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Autoclave Cum Bung Processor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Autoclave Cum Bung Processor Operation & Cleaning Log Book	

9.0 DISTRIBUTION:

- Controlled Copy No. 01 Head Production
- Master Copy Quality Assurance Department

10.0 REFERENCE:

Not Applicable

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

